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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,895	03/31/2004	Tomoko Takeshita	HIRA.0147	5008
7590 REED SMITH LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042		08/22/2007	EXAMINER NOBLE, MARCIA STEPHENS	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/812,895		TAKESHITA ET AL.	
	Examiner		Art Unit	
	Marcia S. Noble		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13, and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 10, 11, 13, and 14 are pending. Claims 10, 11, 13, and 14 are amended by the amendment, filed 6/1/2007. Claims 10, 11, 13, and 14 are under consideration.

Claim Objections

2. Claim 11 stands objected to because of the following informalities: Referring to "The" subject of a previous claim, rather than "A", is proper format for a dependent claim. Accordingly, "A plurality" in claim 11 should read "The plurality".

Appropriate correction is required.

Applicant did not address this objection and therefore it is maintained.

Claim 14 stands objected to because of the following informalities: Referring to "The" subject of a previous claim, rather than "A", is proper format for a dependent claim. Accordingly, "A method" in claim 14 should read "The method".

Appropriate correction is required.

Applicant did not address this rejection and therefore it is maintained.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

3. The rejection of claims 10, 11, and 14 under 35 U.S.C. 112, first paragraph, as containing new matter in its recitation of "wherein relative to a vertical axis" and "identical to an injection amount and injection area in all others of the oocytes", is withdrawn.

The amendment to the claims removes these recitations and therefore render the rejection moot.

However, amended claim 13 still recites "an interaction". There still is not literal support for this recitation and because of its great breadth is unclear as to what "an interaction" is referring.

Applicant traverses the argument on the grounds that "an interaction" is new matter that the specification provides support for this recitation on page 14, line 20 to page 21, line 10. The citation from the specification describes transfection of an oocyte with the histamine receptor 31 gene and expression of said gene by the oocyte. It further discloses that upon the addition of a sample comprising histamine, oocyte expressing the histamine receptor interacts with the histamines of the sample. Therefore, the recitation of "an interaction" is supported by the specification.

Applicant's arguments have been fully considered and are not found persuasive. The specification does not specifically define "an interaction" to be the binding or activation of a receptor expressed by the transfected oocyte with its ligand. Therefore, the meaning of "an interaction" must be given it broadest reason interpretation. In the

instant case, "an interaction" can encompass a physical contact between two or more components with no resultant physiological effect. It could also encompass no physical contact but an indirect influence of one or more factors on other factors. As previously stated, the specification does not provide literal or figurative support for the great breadth of possibilities encompassed by "an interaction", of which a ligand-receptor interaction is only one possibility. Therefore, "an interaction" still encompasses new matter.

New Matter

4. Amended claims 10, 11, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 10 recites, "a Z-axis direction". Applicant states that page 9, lines 2-20, provide support for this recitation. This citation from the specification describes the direction of the Z-axis as a plane of movement for a needle on an apparatus used to inject oocytes. However, this citation does not provide implicit or explicit support for a Z-axis direction as a characteristic of a plurality of oocytes as claimed because the Z-axis is a characteristic of the apparatus not the oocytes. Therefore, the specification as originally filed provides no implicit or explicit support for

"a Z-axis direction" as a structural or functional characteristic of the plurality of oocytes as claimed. Furthermore, the claims do not require the use of the apparatus in the process of these product-by-process claims and therefore given its broadest reasonable interpretation, "a Z-axis direction" could designate any arbitrary plan designation to the oocyte, and therefore, would be unclear to an artisan as to which plane or planes "a Z-axis direction" is referring. Therefore, because the specification does not provide implicit or explicit support for neither the broadest interpretations of "a Z-axis direction" nor "a Z-axis direction" as a characteristic of an oocyte, this recitation introduces new matter.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection

based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Claim Rejections - 35 USC § 112, 2nd paragraph, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13 and 14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 13 still stands rejected as being indefinite because the relationship between the claimed solution and sample is not clear, in part due to a lack of antecedent basis. Applicant has amended claim 13 to now recite, "the mRNA being selected as a sample to encode a protein for initiating an interaction with said solution". This recitation suggests that the mRNA is the sample and that the protein encoded by the sample, not the sample itself, interacts with the solution. However, later in the claim, it recites, "the solution is interacting the sample", which suggests that the solution is interacting with the mRNA and not the protein. Therefore, it is not clear which component is the sample and which component is interacting with the solution. Furthermore, the same recitation recites, "a sample" and the preamble also states "a sample". Therefore, it is unclear if the sample recited in the method steps is the same sample as the sample disclosed in the preamble.

Claim 14 depends from claim 13.

Claim 13 still recites, "measuring an electrical response...thereby discriminating". The metes and bounds of this recitation are indefinite because it is unclear how is being discriminated. Claim 14 depends from claim 13.

Applicant did not address this rejection. Therefore, the rejection is maintained.

Amended claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 11 and 14 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification has failed to provide a definition of what is meant by "substantially" with respect to substantially identical to an injection area. It is unclear how identical, substantially identical to an injection area may be. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1632

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10 and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (5,688,938).

Applicant traverses this rejection on the grounds that Brown et al does not teach all of the limitations of the claims, in particular the process by which the product was made.

Applicant's arguments have been fully considered and are not found persuasive.

As previously stated in the Final Office Action, mailed 8/28/2006, claims 10-12 are drawn to a product that requires an oocyte with mRNA injected into its cytoplasm. As long as the product has the same components it can be produced by any means. Brown discloses oocytes with an mRNA injected into its cytoplasm, thereby meeting the limitations of the claims (see p. 9, par 1 of Final Office Action). Therefore, because Brown et al still teach the limitations of the claims, the rejection of claims 10 and 11 is maintained.

Therefore, because the instant amendment to the claims and Applicant's arguments do not overcome the rejection of record, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

Art Unit: 1632

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. The rejection of claims 10 and 11, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-16, 18, 21, 24 and 26-27 of U.S. Patent No. 6,593,129, is withdrawn.

Applicant filed a terminal disclaimer on 6/1/2007, which was approved on 6/14/2007. Therefore, overcoming the rejection of record, and therefore, the rejection is withdrawn.

7. Claims 10 and 11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/876,551.

Applicant asserts that they intend to abandon 10/876,551 thereby obviating this rejection. However, presently 10/876,551 is still pending. Therefore, the rejection of record is maintained.

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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